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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/520,414

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Raju Adhikari

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Ballard Spahr LLP

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ATLANTA, GA 30309-3915

EXAMINER

DICKINSON, PAUL W

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/520,414	Applicant(s) ADHIKARI ET AL.	
	Examiner PAUL DICKINSON	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 1-10, 13, 15-18 and 23-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11, 12, 14 and 19-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/6/2000, 5/6/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's arguments, filed 7/21/2009, have been fully considered but they are not deemed to be fully persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Response to Arguments

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claim 22 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained for the reasons of record.

Applicant argues that the skilled artisan would understand that "sodium chloride type salts" means the use of a salt as a porogen. Applicant describes porogens at page 22, II. 1-11 of the specification, which include sodium chloride, potassium chloride, and sugar.

Applicant's arguments have been fully considered but are not found persuasive. Although the claims are read in light of the specification, limitations from the specification may not be imported into the claims. The Examiner does not agree that the skilled practitioner would recognize that "sodium chloride type salts" is equivalent to water soluble porogens. There are many possible

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interpretations of this term (a salt containing a sodium cation, a chloride anion, or both; a salt containing cations and anions from the same columns of the periodic table as sodium and chloride; a salt having the same crystal structure as sodium chloride), and there is no reason to limit this to water soluble porogens as even the specification does not make this equivalency. At minimum, "sodium chloride type salts" must be salts. For this reason alone the Examiner does not accept that the skilled practitioner would accept that sugar, which is not a salt, is a sodium chloride type salt. For these reasons, the Examiner maintains that "sodium chloride type salts" renders the claim indefinite and the skilled practitioner would not know what constitutes infringement on the claimed invention.

Claim Rejections - 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claims 11-12 and 19-22 under 35 U.S.C. 102(b) as being anticipated by US 4412033 ('033) is maintained for the reasons of record. The rejection of claims 11-12, 14, and 19-22 under 35 U.S.C. 103(a) as being unpatentable over '033 in view of US 4908406 ('406) is maintained for the reasons of record.

The Declaration filed under 37 CFR 1.132 filed 7/21/2009 is insufficient to overcome the above grounds of rejection.

Applicant argues the following points:

(1) The order of addition of the caprolactone triol, diisocyanate, and pentaerythritol make a difference in the final product. Caprolactone triol + diisocyanate + pentaerythritol (as disclosed by '033) produces a different product than pentaerythritol + diisocyanate + caprolactone triol (as currently claimed).

(2) Applicant's polymers are curable at room temperature. Those of '033 are not.

(3) Applicant's compositions are biodegradable. The composition of '033 are useful as adhesives, coatings, sealants, and the like.

(4) The composition of '033 is not biocompatible.

(5) Applicant's composition has a compressive strength of 0.05-80 MPa and a pore size of 150-300 microns.

Applicant's arguments have been fully considered but are not found persuasive. The Examiner agrees with Applicant that the compound depicted on page 10 (made by Scheme I) and that depicted on page 12 (made by Scheme II) of the reply are different compounds. The compound depicted on page 10 is

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made by adding a stoichiometric excess of diisocyanate to caprolactone triol followed by a stoichiometric excess of pentaerythritol. The compound depicted on page 12 is made by adding a stoichiometric excess of diisocyanate to pentaerythritol followed by a stoichiometric excess of caprolactone triol. The reaction products of Scheme I and II are clearly different compounds. However, the instant claims are not limited to a reaction product made by adding a stoichiometric excess of the isocyanate to a low molecular weight multifunctional core molecule (i.e. pentaerythritol) followed by adding a stoichiometric excess of the soft segment-forming functional oligomer (i.e. caprolactone triol) as illustrated in Applicant's examples. Rather, instant claim 11 also encompasses adding these ingredients in other amounts, including in equal (stoichiometric) amounts (i.e. 1:1:1). It is this embodiment, the embodiment of claim 11 wherein the isocyanate, the low molecular weight multifunctional core, and the soft segment-forming functional oligomer are added in stoichiometric amounts, that is anticipated by '033. This product is (caprolactone triol)₁-(diisocyanate)₁-(pentaerythritol)₁. This product is encompassed by the claimed invention and taught by '033 (see previous office action, pages 4-5, bridging paragraph). The Declaration states at paragraph 21 "... if the reaction of a diisocyanate, poly(caprolactone) triol, and pentaerythritol were perfectly stoichiometric, then the products could be similar". The Examiner agrees with this statement. In '033, the NCO/OH ratio of the polymeric polyol/diisocyanate prepolymer (i.e. caprolactone triol/diisocyanate prepolymer) may vary over a wide range (see col 8, lines 42-48). The amount of curing agent added (i.e. pentaerythritol) may be

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added over a wide molar range to yield the desired NCO/OH ratio in the final product (see col 8, line 58 to col 9, line 2). It is reasonable that embodiments of '033 encompass adding the polymeric polyol (caprolactone triol), diisocyanate, and curing agent (pentaerythritol) in near stoichiometric amounts. It is this embodiment, the embodiment wherein the components are added in stoichiometric amounts, which is indistinguishable from instant claim 11.

The Declaration states regarding adding the components in stoichiometric amounts, that "when poly(caprolactone) triol is first reacted with a diisocyanate, the product mixture formed will comprise unreacted diisocyanate, a plurality of different species of isocyanate capped poly(caprolactone), *inter alia*, mono-, di- and tri-capped species..." (paragraph 22). For the sake of argument, even if caprolactone triol and diisocyanate were added together simultaneously (as suggested by the Declaration), and not through drop-wise addition, the presence of other species present does not distinguish the caprolactone triol-diisocyanate product from the claimed invention. By Applicant's own omission, the reaction product will contain a mono-capped species. This mono-capped species will react with pentaerythritol to form the embodiment of Applicant's claimed invention described above (i.e. (caprolactone triol)₁-(diisocyanate)₁-(pentaerythritol)₁). The presence of other species present does not distinguish this composition from the claimed composition. Instant claim 11 uses open terminology to describe the components of the composition (i.e. comprising). Accordingly, a prior art composition which contains even a single molecule of Applicant's compound would anticipate the instant invention.

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In summary, (caprolactone triol)₁-(diisocyanate)₁-(pentaerythritol)₁ is encompassed by the claimed invention and taught by '033. Accordingly, the above grounds of rejection are maintained. If Applicant believes that adding a stoichiometric excess of the isocyanate to the low molecular weight multifunctional core molecule is what distinguishes Applicant's polymer from '033, then this limitation should be reflected in the claims.

A composition cannot be separated from its properties. '033 does not appreciate that the composition has a compressive strength in the range of 0.05-80 MPa nor that the product has pores in a size range of 150-300 microns. Based on the substantially identical process using identical components, the Examiner maintains that he has a reasonable basis to believe that the properties claimed in the present invention are inherent in the composition of '033 as described above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman/
Primary Examiner, Art Unit 1618

Paul Dickinson
Examiner
AU 1618

November 23, 2009